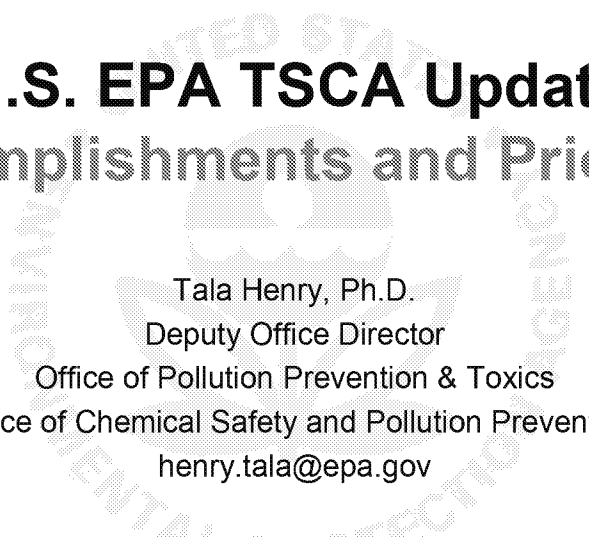




# **U.S. EPA TSCA Update**

## **Accomplishments and Priorities**



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*Presentation to the CPI Polyurethanes Conference*

October 9, 2019

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## **Amended Law**

### **“The Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act”**

- Amended and updated the Toxic Substances Control Act (TSCA)
- Signed by the President on June 22, 2016
- Effective immediately

### **Significance**

- First major update to TSCA in 40 years (1976)
- Passed with overwhelming bipartisan support in both the U.S. House and Senate
- Received support from chemical industry and downstream users of chemicals, NGOs, and other stakeholders

# Amended TSCA: Major Changes

## Framework Rules

- Amended TSCA called for EPA to promulgate four rules (collectively, the “Framework Rules”) to set up the procedures EPA will use to implement, and otherwise align, EPA’s chemical management program with the new requirements and responsibilities in the law:
  - **Active/Inactive Inventory Reporting Rule**
  - **Prioritization Rule**
  - **Risk Evaluation Rule**
  - Fees Rule (no statutory deadline)

## Other new requirements related to:

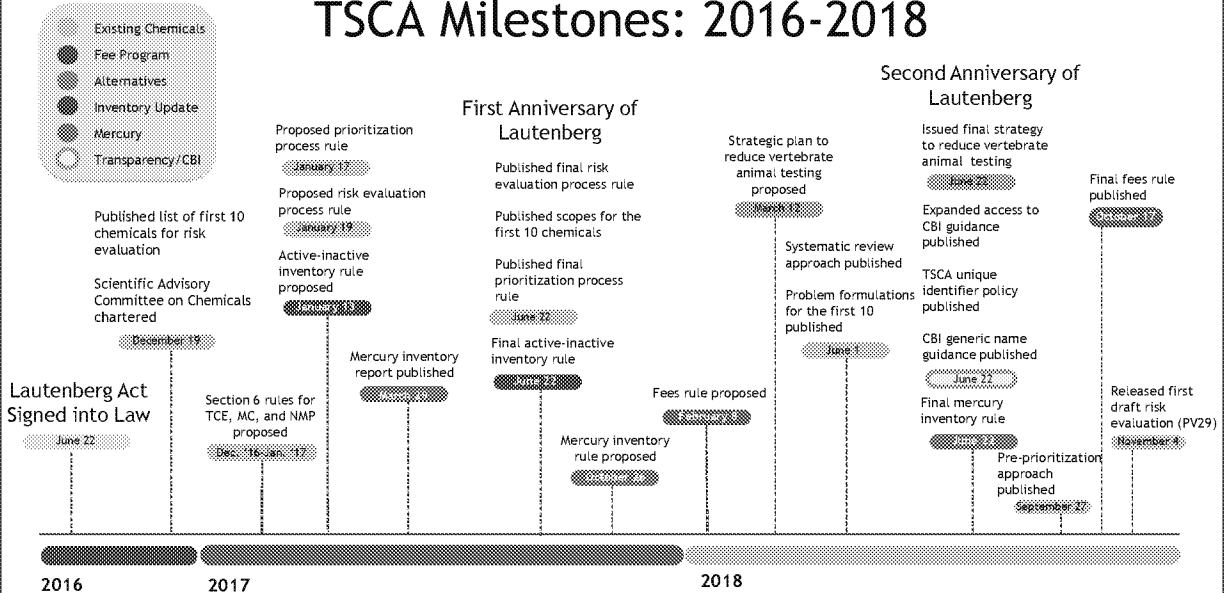
- Existing Chemicals
- New Chemicals
- Confidential Business Information
- Mercury
- Non-animal tests

## **Amended TSCA**

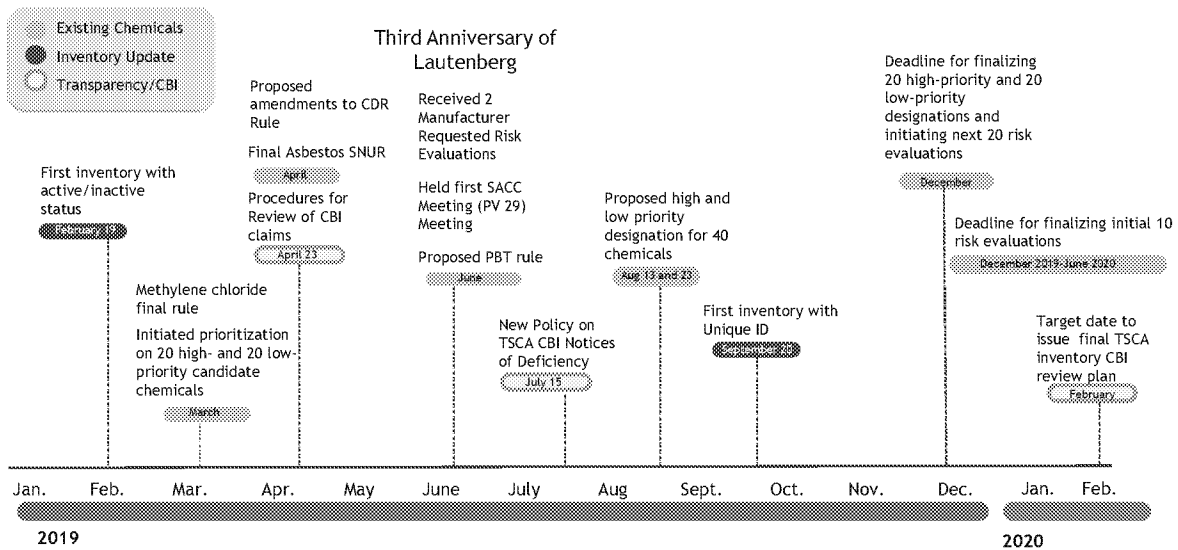
### ***Changes Related to Existing Chemicals***

- Mandatory duty on EPA to evaluate existing chemicals – clear and enforceable deadlines
- Chemical assessment is risk-based; without consideration of costs or other non-risk factors
- Must consider risks to potentially exposed or susceptible subpopulations determined to be relevant to the evaluation
- Unreasonable risks identified in risk evaluation must be addressed
- Expanded authority to more quickly require development of chemical information when needed

# TSCA Milestones: 2016-2018



# TSCA Milestones: 2019 and beyond



# Going Forward

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## Risk Evaluations

- The Agency will use the scientific advice, information and recommendations from the SACC, as well as public comments, to inform the final risk evaluations.
- **PV-29**
  - Public Comment period ended July 10, 2019.
- **HBCD and 1,4-Dioxane**
  - Public comment period ended August 28, 2019.
- **1-Bromopropane**
  - SACC Meeting September 10-12, 2019
  - Public comment period ends October 11, 2019.
- **6 Risk Evaluations**

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## Prioritization

- EPA must begin risk evaluations on 20 high priority chemicals and designate 20 chemicals as low priority by December 22, 2019.
- Draft dossiers for substances designated as high- and low-priority published in the Federal Register for 90-day public comment
  - Low-Priority: August 13, 2019 → November 13, 2019
  - High-Priority: August 23, 2019 → November 21, 2019
  - Also published *Approach Document for Screening Hazard Information for both Low- and High-Priority Substances Under TSCA*
- EPA will issue draft scopes for public comment prior to issuing the statutorily required final scopes 6 months after initiating the risk evaluation.

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## Manufacturer- Requested Risk Evaluations (MRREs)

- TSCA allows chemical manufacturers to request an EPA-conducted risk evaluation of a chemical under 40 CFR 702.31.
- A manufacturer may request that EPA conduct a risk evaluation for conditions of use of interest to the manufacturer.
- EPA has received requests for two phthalates.
- EPA published the requests and possible additional conditions of use identified by EPA in the Federal Register, opened public dockets, and is taking comment until October 3, 2019.
- After the comment period closes the Agency has 60 calendar days to either grant or deny the request.
- EPA looks forward to hearing from the public on the requests themselves as well as the additional conditions of use EPA proposes for inclusion.

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## New Chemicals

- EPA must make an affirmative finding on new chemicals or significant new uses of existing chemicals, before those chemicals can enter the market.
- Reviews underway at time of enactment were considered “resubmitted” and review period restarted; additional notices continued to be received.
- Current focus: Continue to improve processes to meet requirements in law.
  - Issues raised by stakeholders
    - Worker protection
    - Reasonably foreseen conditions of use
    - How much information can be made publicly available

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Recent improvements to transparency include:

EPA is now publishing all new chemical notices and their attachments in Chemview;

EPA is now publishing information about TSCA CBI claim reviews;

EPA has updated its Chemical Review tool, which describes the number of active cases currently under review by EPA and their stage of review.

## New Chemicals Transparency Efforts

- EPA is now publishing all new chemical notices and their attachments in ChemView
- <https://chemview.epa.gov/chemview>

Print | Email | Share

View new Chemical Notice Entry

### New Chemical Notices

Chemical Name: 6-aminocaproic acid, 2,2,2-trifluoroethyl ester  
 (2-oxo-2-((2,2,2-trifluoroethyl)oxy)-6-aminohexanoic acid)  
 Chemical Identifier: P-19-0036  
 Receipt Date of Notice: May 31, 2019

Notice Number: P-19-0036

Type of Notice: Premanufacture Notice (PMN)

Company Name: CBI

Maximum 12-month production volume during the first 5 years/kg/yr: CBI

Type of EPA Review: 90-days

threshold:

- Adoptive for chemicals produced (generic)

All versions (including attachments) of this notice from most recent to original:  
 latest version  
 Version Received: 05/31/2019 (Download PDF)

Chemical Name	Chemical Identifier	Company Name	Maximum 12-month production volume during the first 5 years/kg/yr	Type of EPA Review	threshold
6-aminocaproic acid, 2,2,2-trifluoroethyl ester	P-19-0036	CBI	CBI	90-days	Adoptive for chemicals produced (generic)

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## TSCA CBI Review Statistics

Since the enactment of the TSCA amendments in June 2016, EPA has established numerous new processes, systems, and procedures to enable submitters to provide the information required when making confidentiality claims and to facilitate EPA's review, and where applicable, determinations on these claims. The statistics provided below show EPA's progress toward meeting the requirements of TSCA section 14(g). A "case" is a submission made under a specific section of TSCA and all subsequent submissions and amendments by the same submitter that relate back to the first submission.

CBI Review Statistics (cases received between June 22, 2016 and June 25, 2019)	
Cases in which the specific chemical identity is subject to CBI review	2,177
Cases in which information other than the specific chemical identity is subject to CBI review	2,305
Cases in which both the specific chemical identity and information other than the specific chemical identity is subject to CBI review	587
<b>Total cases subject to CBI review</b>	<b>5,069</b>

Cases resulting in final CBI determinations	
Cases with all CBI claims subject to review, approved	523
Cases with all CBI claims subject to review, denied	5
Cases with CBI claims subject to review, approved-in-part/denied-in-part	34
Cases with all CBI claims subject to review, denial - appeal period pending*	10
<b>Total cases resulting in final CBI determinations</b>	<b>572</b>

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## New Chemicals Transparency Efforts

- EPA is now publishing information about TSCA Confidential Business Information (CBI) claim reviews
- <https://www.epa.gov/tscacbi/statistics-tscacbi-review-program>

## New Chemicals Transparency Efforts

- EPA has updated its Chemical Review Tool

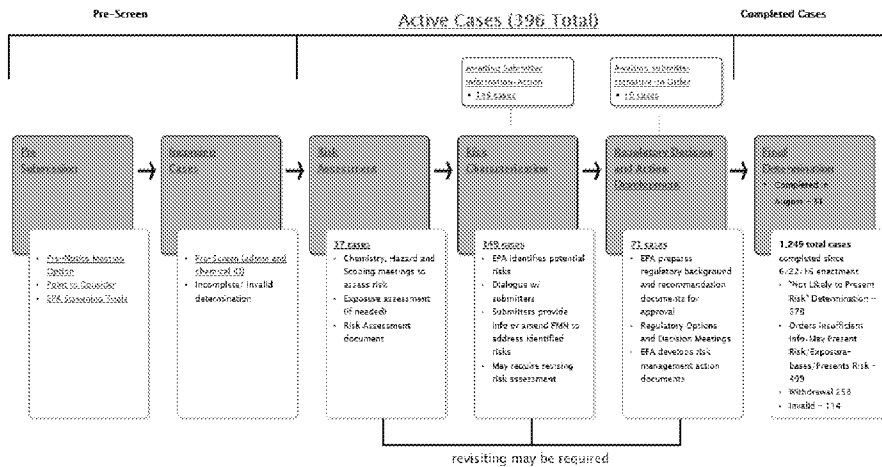
- <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>

The graphic below describes the number of active cases (PMNs, SNUNs, MCANs) currently under review by EPA and their stage of review.

### Active Cases under Review by EPA (PMN/SNUN/MCAN, as of 8/27/2019, 396 cases total)

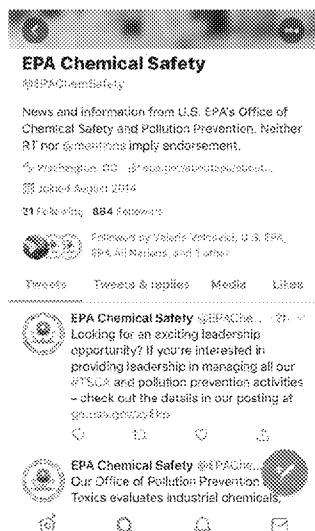
\*To be updated monthly.

To see a list of case numbers in each stage of the review process, click on the number link in the box for that stage. This will open a new tab in your browser window.



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# Social Media



## TSCA Overview:

***Ensuring the Safety of Chemicals  
in our Everyday Lives***



<https://www.youtube.com/watch?v=q3khHQytzco>

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OCSP launched a Twitter account in February 2019 to share the latest news with the public.

Follow us at @EPAChemSafety.

QUESTIONS



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